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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Carl J. Wheeler

Appl. No. 09/937,604

35 U.S.C. §371 Date: September 26, 2001

For: **Adjuvant Compositions and  
Methods for Enhancing Immune  
Responses to Polynucleotide-  
Based Vaccines**

Confirmation No. 2136

Art Unit: 1632

Examiner: Wehbé, Anne Marie Sabrina

Atty. Docket: 1530.0310002/EKS/EJH/ALS

### Reply To Restriction Requirement

Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

Sir:

In reply to the Office Action dated October 1, 2003 (PTO Prosecution File Wrapper Paper No. 8), requesting an election of one group to prosecute in the above-referenced patent application, Applicant hereby provisionally elects to prosecute Group I, represented by claims 1 and 67-77. This election is made without prejudice to or disclaimer of the other claims disclosed.

This election is made **with** traverse.

Applicant asserts that this Restriction Requirement based on lack of unity of invention is unfounded. U.S. Patent and Trademark Office regulations provide guidance to Examiners in regard to unity of invention:

(b) An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combination of categories: . . .

(2) A product and process of use of said product; . . .

37 C.F.R. § 1.475(b)(2).

Furthermore, the Administrative Instructions Under the PCT provide:

(c)(i) If the independent claims avoid the prior art and satisfy the requirement of unity of invention, no problem of lack of unity arises in respect of any claims that depend on the independent claims. In particular, it does not matter if a dependent claim itself contains a further invention. Equally, no problem arises in the case of a genus/species situation where the genus claim avoids the prior art. *Moreover, no problem arises in the case of a combination/subcombination situation where the subcombination claim avoids the prior art and the combination claim includes all the features of the subcombination.*

Administrative Instructions Under the PCT, Annex B, Part I (emphasis added).

The following examples are also provided:

**Example 1**

- Claim 1: A method of manufacturing chemical substance X.
- Claim 2: Substance X.
- Claim 3: The use of substance X as an insecticide.

Unity exists between claims 1, 2 and 3. The special technical feature common to all the claims is substance X.

**Example 15**

- Claim 1: Compound A.
- Claim 2: An insecticide composition comprising compound A and a carrier.

Unity exists between claims 1 and 2. The special technical feature common to all the claims is compound A.

*Id.* at Part 2.

Here, Groups I and II possess unity of invention because all of their respective claims contain reference to the special technical feature, i.e., an adjuvant composition

comprising GAP-DMORIE, a required limitation. The Restriction Requirement does not cite any art to support the allegation of lack of unity of invention.

Claims 78 and 83 of Group II have a combination/subcombination relationship to claim 1 of Group I. In particular, claim 1 is directed to an adjuvant composition comprising GAP-DMORIE, a subcombination. Claims 78 and 83 are combination claims directed to the adjuvant composition comprising GAP-DMORIE *in combination with an* immunogen *or* a container holding one or more antigenic polypeptides, immunogenic polypeptides or polysaccharides, respectively. The above quoted passage from the Administrative Instructions Under the PCT, as well as Example 15, clearly indicate that combination/subcombination claims possess unity of invention where the subcombination claim avoids the prior art and the combination claim includes all the features of the subcombination.

Furthermore, claims 79-82 of Group II are merely methods of use of the adjuvant composition of claim 1 of Group I. As described above, such claims have unity of invention. 37 C.F.R. § 1.475(b)(2). Moreover, claims 79-82 of Group II are related to claim 1 of Group I in the same manner that claim 3 is related to claim 2 in Example 1 shown above.

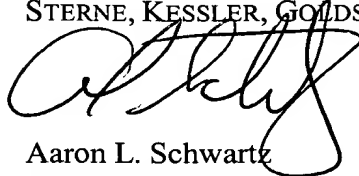
Thus, the Restriction Requirement is improper because unity of invention exists amongst the claims. Reconsideration and withdrawal of the Restriction Requirement, and consideration and allowance of all pending claims, are respectfully requested.

It is not believed that extensions of time are required, beyond those that may otherwise be provided for in accompanying documents. However, if additional extensions of time are necessary to prevent abandonment of this application, then such

extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and any fees required therefor are hereby authorized to be charged to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

A handwritten signature in black ink, appearing to read 'A. Schwartz', is written over the firm name.

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